0.07, was optimal.[771] Similarly, shortly thereafter, Philip Morris introduced the king-size Merit Ultra Lights with an elevated nicotine/tar ratio of approximately 0.10.[772] The king-size Merit Ultra Lights (hard pack) continued to have an elevated nicotine/tar ratio of 0.10 as recently in 1994.[773] According to William Farone, the former director of applied research at Philip Morris, the Merit Ultra Lights is an example of "a blend change incorporating the greater use of higher nicotine tobacco . . . [to] produce *a low tar cigarette with the desired pharmacologically active level of nicotine.*"[774]

These brands do not appear to be isolated examples. The evidence in the record indicates that the design of cigarettes to achieve specific nicotine deliveries is a common practice within the cigarette industry. According to Farone, cigarettes are designed to "attain a *predetermined nicotine/tar ratio.*"[775] Likewise, Ian Uydess, the former Philip Morris scientist, states that "*[n]icotine levels were routinely targeted and adjusted by Philip Morris.*"[776]

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[771] Jones B, Houck W, Martin P (Philip Morris Inc.), *Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication* (Oct. 1975), in 141 Cong. Rec. H8132 (daily ed. Aug. 1, 1995) (emphasis added). *See* AR (Vol. 711 Ref. 6).

[772] Federal Trade Commission, *"Tar," Nicotine, and Carbon Monoxide of the Smoke of 200 Varieties of Cigarettes* (1981). *See* AR (Vol. 535 Ref. 96, vol. III.D).

[773] Federal Trade Commission, *Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes* (1994). *See* AR (Vol. 29 Ref. 485).

[774] Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 10 (emphasis added). *See* AR (Vol. 638 Ref. 2).

[775] *Id.* at 11 (emphasis added).

[776] Declaration of Uydess IL (Feb. 29, 1996), at 8 (emphasis added). *See* AR (Vol. 638 Ref. 1).

e. The Manufacturers Precisely Control Nicotine Deliveries

A principal feature of all marketed cigarettes is the precise control over nicotine delivery achieved by the manufacturers. Annual variations in the nicotine content of raw tobacco leaves originating in the same geographical area can be as high as 100%.[777] Nevertheless, the nicotine deliveries in commercial cigarettes are consistent to a tenth of 1%. *See* 60 FR 41694. This is a high degree of control even for a conventional pharmaceutical company. It does not occur by chance, and the industry does not pretend that it does. The precise control ensures that smokers receive a consistent nicotine dosage within a brand from cigarette to cigarette, pack to pack, and year to year.

The evidence in the record supports a finding that the manufacturers' precise control over nicotine levels reflects the central role of nicotine in cigarette manufacturing. According to the statement of William Farone of Philip Morris, the cigarette industry even developed "complex computer models to help determine nicotine and tar deliveries."[778] These models "allowed blend ingredients, filter and paper components, and numerous other variables to be considered simultaneously" and "enabled product developers to identify which components were required to produce specific nicotine and tar deliveries."[779]

The administrative record demonstrates that the industry pays careful attention to nicotine throughout the manufacturing process. In particular, as described below, nicotine

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[777] Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. IV, at 32. *See* AR (Vol. 535 Ref. 96).

[778] Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 13. *See* AR (Vol. 638 Ref. 2).

[779] *Id.* at 13-14.

plays an essential role in tobacco growing, leaf purchasing, leaf blending, and the manufacture of reconstituted tobacco. This control provides smokers seeking the pharmacological effects of nictine with a remarkably consistent dose of nicotine from cigarette to cigarette.

i. Tobacco Growing. Cigarette manufacturers' ability to control nicotine delivery begins with tobacco growing. Although cigarette manufacturers do not directly control what tobacco farmers grow, they have successfully influenced the characteristics of tobacco crops, including their nicotine content.

As discussed in the Jurisdictional Analysis, cigarette manufacturers were influential in establishing the Minimum Standards Program (MSP) administered by the USDA. This program began in the 1960's in response to the emergence of so-called "discount" varieties of tobacco that had low nicotine contents. The MSP eliminated the discount varieties and helped control the variation in the nicotine content of the tobacco crop by setting minimum and maximum permissible levels of nicotine. *See* 60 FR 41697–41698.

Moreover, tobacco leaf experts have reported that the nicotine level in certain varieties of tobacco rose in response to the needs of cigarette manufacturers. For instance, an expert with a U.S. leaf company observed in 1983 that "[o]nce the manufacturer has expressed a preference for a certain style of leaf, cultural practices can be implemented on the farm to try to fulfill his requirements."[780] According to this expert,

[780] Glass JM, Production and leaf chemistry of burley tobacco in Latin America, in *Recent Advances in Tobacco Science,* 37th Tobacco Chemists' Research Conference (1983), at 81. *See* AR (Vol. 528 Ref. 97, appendix 19).

"a noticeable change has occurred in leaf chemistry" of burley tobacco imported into the United States—"*especially the increase in nicotine levels.*"[781]

ii. Leaf Purchasing. The industry's direct control over nicotine delivery starts with its leaf purchasing decisions. As described in the Jurisdictional Analysis, *see* 60 FR 41703–41706, and as the industry comments themselves confirm, important leaf characteristics in purchasing include "stalk position," "impact," and "smoke quality." These characteristics correlate closely with the nicotine content in the tobacco leaves.

The industry acknowledges that, as a general rule, the relative position of a tobacco leaf on the stalk of the plant will determine the nicotine content in that leaf.[782] The nicotine level usually goes up from the bottom to the top of the stalk. According to Brown & Williamson's comment, "*[h]igher stalk tobacco leaves do have more nicotine than lower stalk leaves on the same plant.*"[783]

The Agency has found that stalk position plays a key role in the leaf purchasing practices of cigarette manufacturers. The industry does not dispute the significance of stalk position. For example, Brown & Williamson does not dispute the Agency's finding that stalk position is the "first thing" Brown & Williamson looks for during leaf purchasing. *See* 60 FR 41705. Similarly, RJR concedes that stalk position is one of the three primary "quality determinants" used by RJR in leaf purchasing.[784] Because of the

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[781] *Id.* at 77 (emphasis added).

[782] R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 44. *See* AR (Vol. 519 Ref. 103).

Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 10. *See* AR (Vol. 529 Ref. 104).

[783] Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 10 (emphasis added). *See* AR (Vol. 529 Ref. 104).

[784] R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 44. *See* AR (Vol. 519 Ref. 103).

relationship between stalk position and nicotine content, when manufacturers select tobacco leaves based on stalk position, they are in effect controlling the nicotine content of the leaves they purchase.

It is also undisputed that "impact" is associated with the nicotine level in a tobacco leaf and that "impact" plays a role in leaf purchasing. RJR, for instance, admits that "impact is . . . an element of any smoking of tobacco, including smoking of samples purchased during the auction season;" and that "nicotine is reported to be a factor" in "impact."[785]

Cigarette manufacturers deny that nicotine plays a role in leaf selection. In their words, "nicotine content is not a principal criterion in the purchase of leaf."[786] The Agency does not find this assertion to be credible. Finished cigarettes have highly consistent nicotine deliveries. This control could not be achieved without taking into account nicotine content in the purchase of tobacco leaves. If nicotine content was not a critical purchasing factor, manufacturers would have no assurance that they were purchasing leaves that could be blended together to provide consistent nicotine deliveries in the finished cigarettes.

iii. Leaf Blending. Leaf blending is one of the primary means the industry uses to control nicotine levels in cigarettes. This is acknowledged by the industry, which states in its joint comment that "[t]obacco is blended for consistency and uniformity. . . ."[787] At

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[785] *Id.* at 43-44.

[786] Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. IV, at 58. *See* AR (Vol. 535 Ref. 96).

[787] *Id.* at 66.

a minimum, therefore, the industry has conceded one of the Agency's points in its Jurisdictional Analysis: blending to ensure "consistency and uniformity" enables the industry to overcome naturally occurring variations in nicotine associated with genetics and soil and climatic conditions. *See* 60 FR 41706.

The joint industry comment provides a graphic representation of the naturally occurring variations in nicotine levels in raw tobacco. The industry's submission shows the rising but substantially fluctuating nicotine levels in flue-cured tobacco from the early 1950's through the early 1990's.[788] Through blending, tobacco manufacturers are able to overcome these variations and produce a remarkably consistent product with uniform nicotine levels.

The central role of blending in ensuring consistent nicotine yields is acknowledged in the industry comments. As Brown & Williamson observes, "the manufacturing challenge is to maintain constancy of product composition not only from day to day, but month to month and year to year despite variation in the raw material."[789]

iv. Reconstituted Tobacco. The tobacco industry also pays careful attention to nicotine during the manufacture of reconstituted tobacco, which makes up about 15% to 25% of the tobacco in cigarettes.[790] The process of manufacturing reconstituted tobacco is described in detail in the Jurisdictional Analysis. *See* 60 FR 41719–41721. The careful management of nicotine in this process allows the manufacturers to control precisely the level of nicotine in reconstituted tobacco.

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[788] *Id.* at Vol. IV, Fig. 1.

[789] Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 17. *See* AR (Vol. 529 Ref. 104).

[790] Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. IV, at 72. *See* AR (Vol. 535 Ref. 96).

The statement of William Farone, the former Philip Morris director of applied research, describes how "the industry has used reconstituted tobacco products to assist in controlling the nicotine delivery in cigarettes."[791] According to Farone:

> By controlling the ingredients that go into making reconstituted tobacco, the industry controls the chemical and physical properties of the finished sheet, *including its nicotine content*. . . . The reconstituted tobacco blend destined for a low tar cigarette can be made with a higher concentration of [high-nicotine] burley tobacco scraps than the blend of reconstituted tobacco designated for a full flavor brand.[792]

Farone also describes how cigarette manufacturers monitor nicotine levels in reconstituted tobacco, stating that "[q]uality control checks involving the use of a gas or liquid chromatography to ascertain the exact nicotine amounts are routinely employed during the process."[793] In its comments, Philip Morris confirms that it regularly measures nicotine levels in reconstituted tobacco. According to Philip Morris' comments:

> Representative periodic sampling is done with respect to all tobacco materials that go into the cigarette manufacturing process—natural leaf tobacco, expanded tobacco, as well as blended and reconstituted leaf. *Such periodic sampling includes measurements of . . . alkaloids or nicotine.*[794]

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[791] Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 12. *See* AR (Vol. 638 Ref. 2).

[792] *Id.*

[793] *Id.*

[794] Philip Morris Inc., Comment (Apr. 19, 1996), at 56 (emphasis added). *See* AR (Vol. 700 Ref. 226).

The Agency also received a declaration relating to reconstituted tobacco from Jerome Rivers, a former supervisor in Philip Morris' Blended Leaf Plant, Declaration of Rivers J (Mar. 7, 1996). *See* AR (Vol. 640 Ref. 3), as well as two affidavits from current Philip Morris employees denying some of Rivers' assertions (Philip Morris Inc., Comment (Apr. 19, 1996), Appendix 3. *See* AR (Vol. 700 Ref. 226)), and supplemental comments relating to Rivers' declaration submitted by Philip Morris after the close of the comment period. Philip Morris Inc., Supplemental Comments (May 30, 1996). *See* AR (Vol. 700 Ref. 1331). After considering Rivers' declaration, the two affidavits, and Philip Morris' original and supplemental comments, the Agency has determined that it will not rely on the Rivers declaration or the two affidavits.

There is also evidence that reconstituted tobacco is used by cigarette manufacturers as a vehicle for the addition of ammonia compounds. An article in the *Wall Street Journal* reports that Philip Morris, Brown & Williamson, and R.J. Reynolds add ammonia to their reconstituted tobacco.[795] According to the article, internal Brown & Williamson documents describe the "nicotine pick-up potential" of ammonia in reconstituted tobacco. The tobacco company documents described in the article state that ammonia added to reconstituted tobacco can scavenge nicotine from the tobacco in the rest of the cigarette, significantly increasing the level of "free nicotine" in the cigarette. One of the documents, a Brown & Williamson competitive analysis of Marlboro, states that ammonia-treated reconstituted tobacco is "the soul of Marlboro."[796]

As a result of the industry's focus on nicotine in the areas described above, as well as in other areas described in the Jurisdictional Analysis, cigarette manufacturers provide smokers seeking the pharmacological effects of nicotine with a remarkably consistent dose of nicotine from cigarette to cigarette.

f. Satisfying Consumer Preferences Requires Controlling and Manipulating Nicotine Deliveries to Satisfy Addiction and Provide Other Pharmacological Effects

The cigarette industry maintains that it does not control and manipulate nicotine deliveries because its sole objective is to design cigarettes that meet consumer preferences. Brown & Williamson, for example, asserts that:

> [I]ts intent is to design, manufacture and market its cigarettes to meet the preferences of adult smokers over competing brands, not to create and maintain addiction. . . . Consumer demand determines

[795] Freedman AM, Tobacco firm shows how ammonia spurs delivery of nicotine, *Wall Street Journal* (Oct. 18, 1995). *See* AR (Vol. 639 Ref. 2).

[796] *Id.*

the content of the tobacco blends used in marketed B&W cigarettes.[797]

Similarly, RJR asserts that it "designs, manufactures, and markets a broad range of cigarette products in response to the . . . demands of adult smokers" and "not . . . to provide smokers with pharmacologically active 'doses' of nicotine."[798]

The Agency agrees that cigarette manufacturers, like other manufacturers of consumer products, design their products to meet consumer demand. The Agency disagrees, however, that this establishes that cigarette manufacturers do not control and manipulate nicotine levels for pharmacological purposes. The unstated premise of the manufacturers' argument is that the consumer demands they seek to satisfy do *not* include a desire for the pharmacological effects of nicotine. This is simply not credible. To the contrary, the Agency finds that what the cigarette manufacturers describe as satisfying consumer preferences is, in reality, providing consumers with cigarettes that sustain consumers' addiction and offer other desired pharmacological effects of nicotine.

It is beyond reasonable dispute that consumers of cigarettes smoke for the pharmacological effects of nicotine, including satisfaction of their addiction. As discussed in sections II.A. and II.B., above, this fact is widely accepted in the scientific community. As discussed in section II.C.2. and 3., above, this fact is also accepted by the cigarette manufacturers' own scientists. The implication of this fact for cigarette design is clear: to compete in the marketplace, cigarette manufacturers must produce cigarettes that sustain

[797] Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 3, 12 (emphasis added). *See* AR (Vol. 529 Ref. 104).

[798] R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 3-4. *See* AR (Vol. 519 Ref. 103).

smokers' addiction and provide the other pharmacological effects of nicotine sought by smokers. Any cigarette manufacturer that failed to provide these pharmacological effects would soon find itself out of business, because addicted smokers and other smokers seeking the pharmacological effects of nicotine would switch to other brands.

Brown & Williamson provides an example of how meeting consumer preferences compels cigarette manufacturers to control and manipulate nicotine. As noted above, Brown & Williamson's comments assert that Brown & Williamson designs its cigarettes to meet "consumer demands." As discussed above in section II.C.2.c., however, the documents in the record from Brown & Williamson and its parent, BATCO, also acknowledge that "*a considerable proportion of smokers depend on the pharmacological action of nicotine for their motivation to continue smoking*"[799] and that "*nicotine plays a predominant role for many smokers.*"[800] Indeed, as recently as 1992, company researchers stated that what "*the smoker clearly wants*" is "*[t]he rapid, peaking intake of nicotine.*"[801] Both Brown & Williamson's assertion that it designs cigarettes to meet "consumer demands" and its acknowledgment that smokers seek "the pharmacological action of nicotine" leads to an obvious conclusion: Brown & Williamson's efforts to meet consumer preferences necessarily require the company to design cigarettes that provide consumers with the pharmacological effects of nicotine.

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[799] Kilburn KD, Underwood JG (BATCO), *Preparation and Properties of Nicotine Analogues* (Nov. 9, 1972), at 2 (emphasis added). *See* AR (Vol. 31 Ref. 524-1).

[800] Green SJ (BATCO), *BAT Group Research* (Sep. 4, 1968), at 2 (emphasis added). *See* AR (Vol. 15 Ref. 192).

[801] *Transdermal Nicotine,* Research and Development/Quality, at 3 (emphasis added). *See* AR (Vol. 531 Ref. 125).